

**UNITED STATES DISTRICT COURT
DISTRICT OF NEVADA**

SPECTRUM PHARMACEUTICALS, INC.)
and UNIVERSITY OF STRATHCLYDE,)

Case No.: 2:12-cv-00111-GMN-NJK

Plaintiffs,
vs.)

ORDER

SANDOZ INC.,
Defendant.

Defendant.)
)

11. *What is the primary purpose of the following statement?*

Pending before the Court is the Motion to Dismiss Defendant’s Inequitable Conduct Counterclaim and Affirmative Defense (ECF No. 100) filed by Plaintiffs Spectrum Pharmaceuticals, Inc. and University of Strathclyde (collectively, “Plaintiffs”). Defendant Sandoz Inc. (“Defendant”) filed a Response (ECF No. 103) and Plaintiffs filed a Reply (ECF No. 106).

I. BACKGROUND

Plaintiff University of Strathclyde (“Strathclyde”) is the owner by assignment of United States Patent No. 6,500,829 (“the ’829 Patent”), entitled “Substantially Pure Diastereoisomers of Tetrahydrofolate Derivatives.” (Compl., ¶ 9, ECF No. 1.) Plaintiff Spectrum Pharmaceuticals is the exclusive licensee of the ’829 Patent. The ’829 Patent generally relates to a substantially pure composition of levoleucovorin, a compound that the Food and Drug Administration (“FDA”) previously approved “to treat patients diagnosed with advanced metastatic colorectal cancer.” (*Id.* ¶ 13.) Plaintiff Spectrum Pharmaceuticals markets this product under the trade name “Fusilev.” (*Id.* ¶ 11.) The alleged infringement relates to Defendant’s filing of an Abbreviated New Drug Application, in which Defendant sought approval from the FDA to

1 market a generic version of Spectrum's pharmaceutical product Fusilev® prior to the expiration
 2 of the '829 Patent. (*Id.* ¶¶ 16-20.)

3 Plaintiffs initiated this action on January 20, 2012. (Compl.) Defendant filed an Answer
 4 on February 15, 2012. (Answer, ECF No. 8.) However, after Plaintiffs made several
 5 representations in their claim construction briefs and during the December 11, 2012 *Markman*
 6 hearing, Defendant filed an Amended Answer on January 25, 2013. (Am. Answer, ECF No. 99.)
 7 In the Amended Answer, Defendant added a sixth affirmative defense for unenforceability due
 8 to inequitable conduct. (*Id.* ¶¶ 6-31.) In addition, Defendant added a third counterclaim for a
 9 declaratory judgment of unenforceability due to inequitable conduct. (*Id.* ¶¶ 24-26.)

10 In response, Plaintiffs filed the instant motion requesting that the Court dismiss
 11 Defendant's Third Counterclaim and requesting that the Court strike Defendant's Sixth
 12 Affirmative Defense. (*See generally* Mot. to Dismiss, ECF No. 100.)

13 **II. LEGAL STANDARD**

14 "On procedural issues, [courts] follow[] the rule of the regional circuit, unless the issue is
 15 unique to patent law and therefore exclusively assigned to the Federal Circuit." *Madey v. Duke*
 16 *Univ.*, 307 F.3d 1351, 1358 (Fed. Cir. 2002). If "the issue pertains to or is unique to patent
 17 law," district courts apply the law of the Federal Circuit "to both substantive and procedural
 18 issues [that are] intimately involved in the substance of enforcement of the patent right." *Flex-*
 19 *Foot, Inc. v. CRP, Inc.*, 238 F.3d 1362, 1365 (Fed. Cir. 2001) (internal quotation marks and
 20 citations omitted).

21 Federal Rule of Civil Procedure 12(b)(6) mandates that a court dismiss a cause of action
 22 that fails to state a claim upon which relief can be granted. *See N. Star Int'l v. Ariz. Corp.*
 23 *Comm'n*, 720 F.2d 578, 581 (9th Cir. 1983). When considering a motion to dismiss under Rule
 24 12(b)(6) for failure to state a claim, dismissal is appropriate only when the complaint does not
 25 give the defendant fair notice of a legally cognizable claim and the grounds on which it rests.

1 *See Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). In considering whether the complaint
 2 is sufficient to state a claim, the Court will take all material allegations as true and construe them
 3 in the light most favorable to the plaintiff. *See NL Indus., Inc. v. Kaplan*, 792 F.2d 896, 898 (9th
 4 Cir. 1986).

5 The Court, however, is not required to accept as true allegations that are merely
 6 conclusory, unwarranted deductions of fact, or unreasonable inferences. *See Sprewell v. Golden*
 7 *State Warriors*, 266 F.3d 979, 988 (9th Cir. 2001). A formulaic recitation of a cause of action
 8 with conclusory allegations is not sufficient; a plaintiff must plead facts showing that a violation
 9 is *plausible*, not just possible. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Twombly*, 550
 10 U.S. at 555) (emphasis added).

11 **III. DISCUSSION**

12 Plaintiffs request that the Court dismiss Defendant's Third Counterclaim for a
 13 Declaratory Judgment of Unenforceability of the '829 Patent because Defendant failed to plead
 14 facts that plausibly establish the materiality element of an inequitable conduct claim. (Mot. to
 15 Dismiss, ECF No. 100.) However, the Court finds that the facts in Defendant's Amended
 16 Answer, when taken as true, plausibly establish that the '829 Patent is unenforceable due to
 17 inequitable conduct. Therefore, Plaintiffs' Motion to Dismiss is **DENIED**.

18 Inequitable conduct arises from the duty of candor that the USPTO imposes on every
 19 individual involved in the filing and prosecution of a patent application. *See* 37 C.F.R. § 1.56(a)
 20 ("Each individual associated with the filing and prosecution of a patent application has a duty of
 21 candor and good faith in dealing with the [Patent] Office, which includes a duty to disclose to
 22 the Office all information known to that individual to be material to patentability as defined in
 23 this section."). Inequitable conduct is an equitable defense to patent infringement that, if
 24 proved, bars enforcement of a patent. *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d
 25 1276, 1287 (Fed. Cir. 2011) (en banc).

1 To plead inequitable conduct, the accused infringer must allege that (1) “the applicant
 2 misrepresented or omitted material information” (2) “with the specific intent to deceive the
 3 PTO.”¹ *Id.* However, because a claim of unenforceability due to inequitable conduct sounds in
 4 fraud, the party alleging inequitable conduct must satisfy the heightened pleading standard of
 5 Rule 9(b) of the Federal Rules of Civil Procedure. *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575
 6 F.3d 1312, 1326-27 (Fed. Cir. 2009). Rule 9(b) requires that “[i]n alleging fraud or mistake, a
 7 party must state with particularity the circumstances constituting fraud or mistake.” Fed. R. Civ.
 8 P. 9(b). Thus, “[a] pleading that simply avers the substantive elements of inequitable conduct,
 9 without setting forth the particularized factual bases for the allegation, does not satisfy Rule
 10 9(b).” *Exergen*, 575 F.3d at 1326-27. At bottom, to satisfy the heightened pleading requirement
 11 of Rule 9(b), the accused infringer must identify “the specific who, what, when, where, and how
 12 of the material misrepresentation or omission committed before the PTO.” *Id.* at 1327.

13 **A. Materiality**

14 In general, to establish the materiality element of inequitable conduct, the applicant’s
 15 misrepresentation to the USPTO must be “the but-for cause of the patent’s issuance.”
 16 *Therasense*, 649 F.3d at 1292. However, the Federal Circuit “recognizes an exception in cases
 17 of affirmative egregious misconduct”; “[w]hen the patentee has engaged in affirmative acts of
 18 egregious misconduct, such as the filing of an unmistakably false affidavit, the misconduct is
 19 material.” *Id.*

20 Defendant’s Amended Answer alleges that, during the prosecution of the application that
 21 eventually issued as the ’829 Patent, the prosecuting attorney committed inequitable conduct in
 22 the form of “affirmative egregious misconduct,” which, after *Therasense*, is “*per se* material to

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 25 ¹ Whether the accused infringer has satisfied the heightened pleading standard of Rule 9(b) in pleading inequitable conduct is governed by Federal Circuit law because “it bears on an issue that ‘pertains to or is unique to patent law.’” *Cent. Admixture Pharmacy Servs., Inc. v. Advanced Cardiac Solutions, P.C.*, 482 F.3d 1347, 1356 (Fed. Cir. 2007).

1 patentability.” (Am. Answer ¶¶ 6-19, ECF No. 99.) Defendant contends that the prosecuting
 2 attorney filed several false declarations related to the number of independent claims in the
 3 application. (*Id.* ¶¶ 8-15.) Specifically, Defendant alleges that the prosecuting attorney routinely
 4 certified to the USPTO that the claim that ultimately issued as claim 13 was a dependent claim,
 5 even though Plaintiffs intended the claim as an independent claim. (*Id.*) Defendant further
 6 asserts that Plaintiffs previously admitted that the prosecuting attorney knew that these
 7 declarations were inaccurate and false, but, nevertheless, filed the declarations in an attempt to
 8 pay a lower filing fee for the patent application.² (*Id.* ¶¶ 16-18.)

9 Plaintiffs vigorously contend that Defendant cannot prove these facts and that these facts
 10 do not amount to affirmative egregious misconduct. However, at the motion to dismiss stage,
 11 the Court does not weigh the alleged facts and consider whether Defendant will ultimately
 12 prevail on this cause of action. The Court need only determine, assuming the alleged facts as
 13 true, whether the Amended Answer establishes a plausible material misrepresentation.
 14 Accordingly, based on the facts alleged in the Amended Answer, the Court concludes that
 15 Defendant has plausibly established the materiality element of inequitable conduct; Defendant
 16 has plausibly stated “the specific who, what, when, where, and how of the material
 17 misrepresentation or omission committed before the PTO.” *Exergen*, 575 F.3d at 1327.

18 **B. Intent**

19 Accused infringers must also plead with particularity facts from which a court may
 20 reasonably infer that a specific individual knew of this material information and deliberately

22 ² Defendant also notes that “[s]igning any paper for presentation to the PTO constitutes a certification that ‘[a]ll
 23 statements made therein of the party’s own knowledge are true, all statements made therein on information and
 24 belief are believed to be true, and all statements made therein are made with the knowledge that whoever, in any
 25 matter within the jurisdiction of the Office, knowingly and willfully falsifies, conceals, or covers up by any trick,
 scheme, or device a material fact, or knowingly and willfully makes any false, fictitious, or fraudulent statements
 or representations, or knowingly and willfully makes or uses any false writing or document knowing the same to
 contain any false, fictitious, or fraudulent statement or entry, shall be subject to the penalties set forth under 18
 U.S.C. 1001 and any other applicable criminal statute, and violations of the provisions of this section may
 jeopardize the probative value of the paper.’” (Am. Answer ¶ 18 (quoting 37 C.F.R. 11.18(b).))

1 withheld it with the specific intent to deceive the PTO. *Exergen*, 575 F.3d at 1328. “A
 2 reasonable inference is one that is plausible and that flows logically from the facts alleged,
 3 including any objective indications of candor and good faith. *Exergen*, 575 F.3d at 1329 n.5.

4 In this case, Defendant alleged that “Plaintiffs admitted in their September 17, 2012
 5 Reply Claim Construction Brief . . . that ‘[i]ndependent claims like claim 13 [of the ’829 patent]
 6 were a well-known loophole to avoid paying the independent-claim fee.’” (Am. Answer ¶ 16.)
 7 Defendant further alleges that “Counsel for Plaintiffs admitted at the December 11, 2012 claim
 8 construction hearing that during prosecution of the ’829 patent the ‘inventors took advantage’ of
 9 the way the PTO examined claims for the purpose of fee calculation ‘to avoid paying
 10 independent claim fees.’” (*Id.* ¶ 17.)

11 Accordingly, the Court finds that Defendant’s Amended Complaint alleges sufficient
 12 facts from which the Court can reasonably infer that the prosecuting attorneys acted with the
 13 specific intent to deceive the patent examiner.

14 **IV. PLAINTIFFS’ MOTION TO STRIKE**

15 In Plaintiffs’ motion, Plaintiffs also requests that this Court strike Defendants’ Sixth
 16 Affirmative Defense, which alleges that the ’829 Patent is unenforceable due to inequitable
 17 conduct. (Pl.’s Mot. to Dismiss, ECF No. 99.)

18 “[T]he function of a 12(f) motion to strike is to avoid the expenditure of time and money
 19 that must arise from litigating spurious issues by dispensing with those issues prior to trial . . .”
 20 *Sidney-Vinstein v. A.H. Robins Co.*, 697 F.2d 880, 885 (9th Cir. 1983).³ Rule 12(f) of the
 21 Federal Rules of Civil Procedure provides that a “court may strike from a pleading an
 22 insufficient defense or any redundant, immaterial, impertinent, or scandalous matter.” Fed. R.
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24
 25 ³ A grant or denial of a motion to strike is not an issue unique to patent law. Therefore, courts apply the law of
 the regional circuit where appeals from the district court would normally lie. *Anchor Wall Sys., Inc. v. Rockwood
 Retaining Walls, Inc.*, 340 F.3d 1298, 1313 (Fed. Cir. 2003).

1 Civ. P. 12(f). A defense is insufficiently pleaded if it fails to give the plaintiff fair notice of the
2 nature of the defense. *See Wyshak v. City Nat'l Bank*, 607 F.2d 824, 827 (9th Cir.1979).

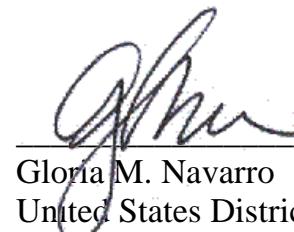
3 In this case, Plaintiffs assert that the Court should strike Defendants' Sixth Affirmative
4 Defense only because it is an insufficient defense. (*See generally* Pl.'s Mot. to Dismiss 2:7-9,
5 ECF No. 99.) As discussed above, the Court finds that Defendant adequately pleaded the
6 counterclaim that corresponds to Defendant's Sixth Affirmative Defense. Therefore, the Court
7 denies Plaintiffs' Motion to Strike Defendant's Sixth Affirmative Defense for the same reasons
8 the Court denies Plaintiffs' Motion to Dismiss Defendant's Third Counterclaim. The allegations
9 in Defendant's Amended Answer are sufficient to provide Plaintiffs with fair notice of the
10 nature of the defense.

11 **V. CONCLUSION**

12 **IT IS HEREBY ORDERED** that Plaintiffs' Motion to Dismiss Defendant's Inequitable
13 Conduct Counterclaim and Affirmative Defense (ECF No. 100) is **DENIED**.

14 **DATED** this 30th day of September, 2013.

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Gloria M. Navarro
United States District Judge